K110637

510(K) SUMMARY

SEP - 7 2011

SPONSOR

LifeScan Europe, a Div. of Cilag GmbH International
Landis and Gyr Strasse 1
Zug, Switzerland 6300.

CORRESPONDENT

Fiona Leeper
LifeScan Scotland Ltd.
Beechwood Park North
Inverness, IV2 3ED, UK
Phone: +44(0) 1463 721596 /e-mail: fleeper@its.jnj.com

Alternate 510(K) Contact
Amy Smith
200 Lawrence Drive
West Chester
PA, 19380
Phone: +1 484 568-1257/e-mail: asmith21@its.jnj.com

DEVICE NAME AND CLASSIFICATION

Trade Name: OneTouch® Verio™IQ Blood Glucose Monitoring System
Common name: Glucose Test System
Classification:
OneTouch® Verio™IQ Blood Glucose Meters and OneTouch® Verio™ Test Strips are Class II devices (21 CFR § 862.1345, Product Code NBW, LFR)

OneTouch® Verio™ Control Solutions are Class I devices (21 CFR § 862.1660), Product Code JJX

SYSTEM DESCRIPTION

The OneTouch® Verio™IQ Blood Glucose Monitoring System consists of the OneTouch® Verio™IQ Blood Glucose Meter, OneTouch® Verio™ Test Strips, OneTouch® Verio™ Mid and High Control Solutions, Lancing Device, Sterile Lancets and Alternative Site testing Kit (available separately). The Alternative Site Testing Kit comprises the OneTouch® Lancing Device, OneTouch® UltraSoft™ Sterile Lancets, OneTouch®, Clear Cap and Instructions for Use. The OneTouch® Verio™IQ Blood Glucose Monitoring System measures the glucose content of a blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement.

PREDICATE DEVICE

OneTouch® Verio™ Blood Glucose Monitoring System (K093745)

INTENDED USE/INDICATIONS FOR USE

The OneTouch® Verio™IQ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The OneTouch® Verio™IQ Blood Glucose Monitoring System is intended to be used by a single patient and should not be used for testing multiple patients.

OneTouch® Verio™IQ Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The OneTouch® Verio™IQ Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The OneTouch® Verio™ Test Strips are for use with the OneTouch® Verio™IQ Blood Glucose Meter to quantitatively measure glucose drawn from the fingertips, forearm or palm.

The OneTouch® Verio™ Control Solutions are for use with the OneTouch® Verio™IQ Blood Glucose Meter and the OneTouch® Verio™ Test Strips to check that the meter and test strips are working together properly and that the test is performing correctly..

COMPARISON TO PREDICATE DEVICE

The Subject device is different from the predicate device for the following aspects:

- **Meter**: ergonomic/physical design, user interface, hardware, modified electronic and software changes.

There are no changes to the OneTouch® Verio™ Test Strips or the OneTouch® Verio™ Mid and High Control Solutions as a result of this 510k submission.

There have been no changes to the intended use, operating principle or scientific technology.

TECHNOLOGICAL CHARACTERISTICS

There has been no change to the fundamental scientific technology, which is amperometric detection. The operating principle remains electrochemical reaction.

SUMMARY OF PERFORMANCE CHARACTERISTICS

The OneTouch® Verio™IQ Blood Glucose Monitoring System (meter, strips, and control solutions) was tested in accordance with ISO 15197:2003(E). Analytical performance testing included system accuracy, repeatability, intermediate precision and linearity testing. A user performance evaluation assessed accuracy of results and usability of the device in the hands of intended users. The OneTouch® Verio™IQ Blood Glucose Monitoring System performed similarly to both the predicate device as well as to a laboratory reference method, the Yellow Springs Instrument (YSI).

System Accuracy

A comparison of system accuracy performance demonstrated that the OneTouch® Verio™IQ Blood Glucose Monitoring System and the OneTouch® Verio™ Blood Glucose Monitoring System are substantially equivalent.

System Accuracy Results for Glucose Concentrations <75 mg/dL
Number (and percent) of meter results that match the laboratory test

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
88/102 (86.3%)	102/102 (100.0%)	102/102 (100.0%)

System Accuracy Results for Glucose Concentrations ≥75 mg/dL
Number (and percent) of meter results that match the laboratory test

Within ±5%	Within ±10%	Within ±15%	Within ±20%
358/498 (71.9%)	465/498 (93.4%)	487/498 (97.8%)	498/498 (100.0%)

Regression Statistics
Samples were tested in duplicate on three test strip lots. Results indicate that the OneTouch® Verio™IQ System compares well with a laboratory method.

# of Subjects	# of Tests	Slope	Intercept (mg/dL)
100	600	0.948	4.732

95% CI Slope	95% CI Intercept	Std. Error ($S_{y.x}$)	R^2
0.941 to 0.955	3.265 to 6.199	9.840	0.991

Precision
Within Run Precision (300 Venous Blood Tests)

Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
40	42.39	1.21	2.86
100	97.43	1.84	1.89
130	130.24	2.49	1.91
200	196.15	3.96	2.02
350	330.34	7.39	2.24

Results show that the greatest variability observed between test strips when tested with blood is 2.86% or less.

Total Precision
(600 Control Solution Tests)

Glucose Level Ranges (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Low (38-62)	50.31	1.77	3.52
Mid (102-138)	117.14	2.70	2.31
High (298-403)	342.34	8.68	2.53

User Performance Evaluation
Subject and HCP Fingertip Results for Glucose Concentrations <75 mg/dL

Tester	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
Subject	18 of 31 (58.1%)	31 of 31 (100%)	31 of 31 (100%)
HCP	23 of 31 (74.2%)	29 of 31 (93.5%)	31 of 31 (100%)

Subject and HCP Fingertip Results for Glucose Concentrations ≥75 mg/dL

Tester	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Subject	159 of 245 (64.9%)	229 of 245 (93.5%)	243 of 245 (99.2%)	244 of 245 (99.6%)
HCP	156 of 245 (63.7%)	228 of 245 (93.1%)	244 of 245 (99.6%)	245 of 245 (100%)

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Alternate Site Testing

Subject AST Results for Glucose Concentrations <75 mg/dL

Site	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
Palm	6/8 (75.0%)	8/8 (100%)	8/8 (100%)
Forearm	4/7 (57.1%)	6/7 (85.7%)	7/7 (100%)

Subject AST Results for Glucose Concentrations ≥75 mg/dL

Site	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Palm	80/154 (51.9%)	132/154 (85.7%)	146/154 (94.8%)	150/154 (97.4%)
Forearm	66/144 (45.8%)	110/144 (76.4%)	127/144 (88.2%)	138/144 (95.8%)

Design verification and validation testing confirmed that the performance, safety, and effectiveness of the OneTouch® Verio™IQ Blood Glucose Monitoring System was equivalent to that of the predicate device. The OneTouch® Verio™IQ Meter met recognized electrical and safety standards.

CONCLUSIONS

The OneTouch® Verio™IQ Blood Glucose Monitoring System is substantially equivalent in its intended use, performance, safety, effectiveness and the underlying scientific and operating principles used, to the predicate OneTouch® Verio™ Blood Glucose Monitoring System (K093745).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 07 2011

Cilag Gmbh International
LifeScan Europe
c/o Fiona Leeper
Regulator Affairs Specialist
Landis and Gyr Strasse 1
CH-6300 Zug, Switzerland

Re: k110637
Trade Name: OneTouch® Verio™ IQ Blood Glucose Monitoring System
Regulation Number: 21 CFR § 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: LFR, NBW
Dated: August 19, 2011
Received: August 24, 2011

Dear Ms. Leeper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K110637

Device Name: OneTouch® Verio™IQ Blood Glucose Monitoring System

Indications for Use:

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The OneTouch® Verio™ Test Strips are for use with the OneTouch® Verio™IQ Blood Glucose Meter to quantitatively measure glucose drawn from the fingertips.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

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